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EUROPEAN PRECIOUS METALS FEDERATION
FOR INFORMATION

19 December 2014

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: FYI Processing
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
UNITED STATES

19 December 2014

Dear Sir/Madam,

RE: For Your Information: Diammonium hexachloroplatinate (CAS number: 16919-58-7)

The European Precious Metals Federation on behalf of its members is providing information on the repeat dose toxicity study findings on Diammonium hexachloroplatinate (CAS number: 16919-58-7).

The kidney has been previously characterised as target organ for soluble platinum compounds including tetra- and hexachloroplatinate compounds.

A 28-day repeat dose oral toxicity study of Diammonium hexachloroplatinate in CD rats has been conducted under the direction of the Precious Metals and Rhenium Consortium c/o European Precious Metals Federation aisbl (PMC c/o EPMF), Brussels, Belgium as part of the integrated testing strategy developed to fulfil the information requirements for the classification and labelling notification and REACH Registration Dossier of the above substance under Directive 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Directive 2008/112/EC of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP). The study conformed to the requirements of OECD Guideline 407. In this study Diammonium hexachloroplatinate showed evidence of nephrotoxicity at 30 mg/kg b.w./day and at 100 mg/kg b.w./day. This was mainly characterized by histopathological lesions in the kidneys in form of hyaline casts, fibrosis, tubular basophilia, lymphocytic infiltration, tubular dilation, and/or tubular necrosis, which occurred in a dose-dependent manner. Statistically significant increases in absolute and relative kidney weights were also evident at 100 mg/kg b.w./day. The treatment related changes affected both sexes.

~ *a member of Eurométaux* ~
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In this study, the no-observed-adverse-effect-level (NOAEL) was established at 10 mg/kg b.w./day.

These findings are congruent with some previously published reports of kidney effects determined in various experimental toxicology studies on soluble platinum compounds, including chloroplatinate salts, and therefore EPMF does not believe that the findings represent "new information" within the definitions of TSCA Section 8(e). However, the submitter considers that the test outcome improves the overall knowledge base in this area, and hence EPMF is voluntarily sharing it with EPA on an FYI basis. This submission should therefore discharge any Section 8(e) responsibilities that might exist, and can be processed in accordance with EPA's procedures.

If you have any questions, please contact:

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Sincerely,

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